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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,009	05/30/2001	Hisashi Kashima	JP920000069US1	8419

7590

01/27/2003

Casey August  
IBM Corporation  
Intellectual Property Law Dept.  
P.O. Box 218  
Yorktown Heights, NY 10598

EXAMINER

SMITH, CAROLYN L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 01/27/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/870,009

Applicant(s)

KASHIMA ET AL.

Examiner

Carolyn L. Smith

Art Unit

1631

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 6, 7, 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 5 and 8-12 is/are rejected.
- 7) ☐ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) 1-14 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' election without traverse of Group V (claims 5-14) and Species A (an intergenic region) in Paper No. 5, filed 11/21/02, is acknowledged. Claims 1-4 are withdrawn from consideration as being drawn to non-elected Groups.

In Restriction Paper No. 4, mailed 10/21/02, the specie election was inadvertently sent with the generic claim assessment. This oversight is hereby corrected. Claims 6-7 and 13-14 are withdrawn from consideration as being drawn to non-elected species.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to a method of identifying the source of genetic information in DNA whereas in contrast the elected claims include DNA and cells.

The corrected or substitute drawings in Paper No. 6, filed 11/21/02, have been accepted.

Claims 5 and 8-12 are herein under examination.

### ***Specification***

The disclosure is objected to because of the following informalities: improper commas and semicolon on page 6, lines 22 and 23.

Appropriate correction is required.

### ***Claim Objections***

Claim 9 is objected to because of the following informalities: incorrect grammar that can be corrected by adding "a" or "the" preceding "multiple" or various other grammatically correct possibilities.

Art Unit: 1631

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5 and 8-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 5 and 8-12, as written do not sufficiently distinguish over nucleic acids and cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. It is acknowledged that insertion of special and non-natural sequences is described in the specification but not particularly in the claims. Thus, one interpretation of the claims is that they are inclusive of DNAs wherein a watermark sequence is merely recognized in a naturally occurring DNA. In the absence of the hands of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980).

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 8-12 recite the phrase "correlated with" which is vague and indefinite. For example, it is unclear what is meant by the sequence being correlated with information as this could be in a mathematical sense or connected in some other fashion. Claims 9 and 10 are also rejected due to its dependency from claim 8. Clarification of the metes and bounds of this phrase via clearer claim wording is required.

Claims 5 and 12 recite the phrase "source of genetic information that is transmitted by said gene portion" which is vague and indefinite. It is unclear what is meant by the source of genetic information as this could pertain to entities such as a particular organism or a particular cell. It is further unclear in the current claim wording what is meant by gene transmitting as it sounds like the gene is giving off some sort of substance or signal. Clarification of the metes and bounds of this phrase via clearer claim wording is required.

Claim 12 recites the phrase "a cell constituting an organism" which is vague and indefinite. It is unclear if the intended concept is that the cell makes up the organism meaning that the only organisms that apply to this situation are unicellular organisms or if the cell is merely one part of the organism. To better convey what this claim is envisioned to contain, clearer claim language is required.

#### ***Claim Rejections – 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1631

Claims 5 and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Oliver et al. (P/N 5,723,765).

Oliver et al. teach sequences that can be introduced into a plant (col. 2, lines 25-27) so that a recombinase gene (a gene portion) and a promoter (a portion containing no genetic information) are present in the DNA (col. 2, lines 41-42). Oliver et al. teach the promoter can be from viral, bacterial, fungal, animal, or plant origin (col. 4, lines 5-7). The Examiner interprets the "source identification information" to mean information identifying a particular gene. As Oliver et al. teach a Lea promoter containing a specific known sequence (see Example 2, col. 9, lines 50-67, where specific primers were made on either side of the promoter sequence), this promoter is inherently correlated with information pertaining to the gene transmitting genetic information as stated in claim 5, because the gene and promoter are considered to be operably linked on the same strand of DNA (col. 4, lines 17-18).

Oliver et al. teach DNA with promoter sequences correlated with "source identification information" (see previous paragraph) where the gene is expressed when a "transiently-active promoter becomes active in the normal course of growth and development" (col. 2, lines 46-51 and col. 4, lines 1-4), which the Examiner interprets to mean the promoter does not affect the regular transmission of genetic information by the gene as stated in claims 8 and 11. As "special sequence" is undefined in the specification, the Examiner interprets it to mean any selected sequence.

Oliver et al. teach introducing a series of functionally interrelated DNA sequences, containing promoters and genes (col. 2, lines 65-67 and col. 3, lines 1-41). As each promoter may include a specific sequence with a specific nucleotide assembly pattern, the Examiner

Art Unit: 1631

interprets the presence of several of these sequences to represent the "multiple types of patterns" as stated in claim 10. Oliver et al. teach the promoters, or "special sequence[s]" in this case, are located in predetermined locations of DNA as stated in claims 9 and 10, as seen in Example 5 (col. 12, lines 40-45) where a 35S promoter was isolated and subcloned back into pMM23 to yield pMM23tet30, where the coding sequence was flanked by the promoter. Oliver et al. teach this construct being introduced into cotton cells (col. 14, lines 7-10), as stated in claim 12. Thus, Oliver et al. anticipate the instant invention.

### ***Conclusion***

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Art Unit: 1631

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 7, 2003

  
ARON H. MARSCHEL  
Examiner